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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,561	12/08/2003	Sharad K. Govil	MTI 3.0-025 DIV DIV	4254

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EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/730,561	GOVIL ET AL.	
	Examiner	Art Unit	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67,69-76,78-111 and 113-119 is/are pending in the application.
- 4a) Of the above claim(s) 29-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28,67,69-76 and 78-111, 113-119 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 67, 69-76, 78-88, 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miranda et al (US 5,474,783).

Miranda et al teach a transdermal comprising a drug, an acrylate polymer and a polysiloxane (abstract). 2-96% polyacrylate and 98-4% polysiloxane is disclosed (column 4 lines 10-12). The acrylate polymer is composed of at least 50% alkyl acrylate monomer (column 9 lines 38-40). Butyl acrylate is disclosed (column 9 line 44). The drug is 0.3-50% of the composition (column 8 line 67-column 9 line 2). Selegiline (a liquid) is disclosed (column 12 line 29). Propylene glycol and alcohols are disclosed as optional cosolvents (column 13 lines 43-54, Table II).

It would have been obvious to one of ordinary skill to make a composition comprising an acrylate to deliver selegiline to achieve the beneficial effect of transdermal delivery in view of Miranda et al. As to the claimed hydrophobic acrylic polymer, Miranda et al teach at least 50% butyl acrylate as cited above, which renders the polymer hydrophilic.

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Upon further review of the prior art in view of applicants' amendments and arguments, the rejection is maintained. Applicants argue that the claims exclude low volatility solvents which remain present after drying between certain temperature ranges. However, as noted above, such solvents are merely optional in the obvious composition.

Claims 67, 69-70, 72, 73, 76, 78-79, 81, 82, 85-88, 91-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sablotsky (US 4,994,267).

Sablotsky teaches a transdermal comprising an acrylic polymer, a synthetic rubber, and a crosslinking agent (abstract). 5-95% acrylic polymer is specified (column 3 line 68-column 4 lines 1-2). At least 50% alkyl acrylate is specified (column 4 lines 20-21). Butyl acrylate is disclosed (column 4 lines 24-25). Polyisobutylene is disclosed as a rubber (column 5 lines 30-37). Nitroglycerin (a liquid) is specified as a drug (column 5 line 65). 0.1-50% drug is disclosed (column 6 lines 38-39). Optional cosolvents, including propylene glycol and alcohols, are disclosed (column 7 lines 58-65).

It would have been obvious to one of ordinary skill to make a composition comprising an acrylate to deliver a drug to achieve the beneficial effect of transdermal delivery in view of Sablotsky. The statements as well as the response to applicants' argument following the first 103 motivation to combine are incorporated herein as applied to Sablotsky.

Upon further review of the prior art in view of applicants' amendments and arguments, the rejection is maintained. Applicants argue that the claims exclude low volatility solvents which remain present after drying between certain temperature ranges. However, as noted above, such solvents are merely optional in the obvious composition.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 8-10, 12-15, 18-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lhila et al (US 5,498,417).

Lhila et al teach a transdermal comprising a pressure-sensitive adhesive (abstract). Gelva 788 [disclosed in applicants' specification in example 15 and tables II and III] is specified (column 2 line 26). 25-90% polymer is disclosed (column 2 lines 28-30). 0.5%-15% each of triethanolamine and glycerol or polyalkylene glycol are disclosed (column 2 lines 39-52). Propylene glycol is specified (claim 1). 10-60% active is disclosed (column 2 lines 33-35).

Applicants argue that Lhila et al do not teach the claimed solvent properties, however, such properties must be possessed by the anticipatory composition because it is the same as that claimed. Applicants simply deny this proposition, an *ipse dixit* argument.

Claims 1-9, 11-14, 16-28, 67, 69-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolter et al (US 5,462,746).

Wolter et al teach a transdermal comprising an adhesive, a drug or salt thereof, and, when the salt is present, an element containing basic groups (abstract). Deprenyl (selegeline) is disclosed (column 3 line 44). Ethyl acetate is specified (column 4 line 64). Glycerol, an optional solvent, is disclosed (column 2 line 55). DURO-TAK 2516 [disclosed in applicants' specification in Table III as an acrylate polymer comprising ethylhexyl acrylate and methyl

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acrylate, crosslinked with aluminum] is specified (column 5 line 9). Polydimethylaminoethyl methacrylate (Eudragit E) is disclosed (column 5 line 1-3). Ethanol is disclosed (column 5 lines 10-11).

It would have been obvious to one of ordinary skill to make a composition comprising deprenyl and an acrylate polymer to achieve the beneficial effect of transdermal delivery in view of Wolter et al. As to the claimed acrylate polymer, deprotonating agent, drug and solvent, it is argued that the composition is achieved when the drug and solvent of Wolter et al enter the matrix of DUROTAK 2516 and Eudragit E (see column 4 line 57-column 5 line 25). As to the claimed percent ranges of of acrylate polymer, non-aqueous solvent and drug, Wolter et al teach suitable amounts. Absent a showing of criticality, optimum suitable amounts may be obtained by routine experimentation.

Applicants argue that high volatility and low volatility solvents are present in the obvious composition. However, the low volatility solvents are optional. Further, as applicants themselves point out, the high volatility solvents are ultimately removed. Applicants argue but do not disclaim two layers.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-14, 17-21, 24-28, 67, 69-111, 113-119 are rejected under 35 U.S.C. 102(e) as being anticipated by Mantelle et al (US 6,316,022).

Mantelle '022 teaches a transdermal comprising a liquid active and a polymer (abstract). Duro-Tak 87-2852 is disclosed (column 13 line 34), the same polymer as applicants teach (page 19 line 18). Selegiline is disclosed (column 3 line 6). Propranolol is specified (column 5 line 12). Propylene glycol is disclosed (column 5 line 67). Rubber and polysiloxanes are disclosed (column 8 lines 47, 61). 10-90% acrylate and 1-40% drug is specified (column 9 table 1). Ethanol and ethyl acetate are disclosed (column 10 lines 60 and 62). 15% selegiline is specified (example 1). Urea is specified (column 6 line 5).

Applicants arguments that they overcome the rejection with a declaration under 35 USC 131 are moot in view of the fact that the declaration supplied is a copy of that directed to the parent rather than an original directed to the instant application.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 67-75 and 94-95, 101-102, 105-111, 113, 115, 119 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 84, 86-94 and 64-80 respectively of copending Application No. 08/883075 and 09/754909 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims encompass the '075 claims regarding the presence of additional unspecified essential ingredients and the patented claims and the '909 claims encompass the instant claims regarding the scope of the alkyl acrylates.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants appear to have overlooked this rejection in their response filed 5/2/06.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633.


The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor J. Richter, can be reached on 571-272-06246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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